

PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substi	tute for form 1449/PTO			Complete if Known		
				Application Number	10/802,540-Conf. #4023	
INI	FORMATION	I DIS	CLOSURE	Filing Date	March 16, 2004	
ST	ATEMENT E	BY A	PPLICANT	First Named Inventor	Pepinsky, Blake R.	
				Art Unit	1647	
	(Use as many she	eets as i	necessary)	Examiner Name	Hamud, F.M.	
Sheet	1	of	1	Attorney Docket Number	BII-00802	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

		FOREIC	ON PATENT	DOCUMENTS		
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (# known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was,filed after June 30, 2003 or is available in the IFW. *Inplicant's unique citation designation number (optional). *Zee Kinds Codes of USPTO Patent Documents at www.uspto.gog or MPEP 901.04. *Senter Office that Issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. *Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
/FH/	CA	Jacobs, et al., "Intramuscular Interferon Beta-1a for Disease Progression in Relapsing Multiple Sclerosis" Annals of Neurology 39 (3): 285-294 (1996)				
/FH/	CB	Nightingale, S.L., "New Multiple Sclerosis Product Licensed" JAMA 270 (14): 1672 (1993)				
/FH/	CC	Katre, N.V., "The Conjugation of Proteins With Polyethylene Glycol and Other Polymers" Advance Drug Delivery Reviews, (10): 91-114 (1993)				
/FH/	CD	Partial European Search Report dated July 26, 2006				

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	/Fozia Hamud/	Date	05/02/2007
Signature	// UZIa i lailiuu/	Considered	00/02/2001

Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

OLI 19 1006 PE

PTO/SB/08a/b (07-06)
Approved for use through 09/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Su	bstitute for form 1449A/B/F	PTO		Complete if Known		
"				Application Number	10/802,540-Conf. #4023	
11	NFORMATIO	N DI	SCLOSURE	Filing Date	March 16, 2004	
5	STATEMENT BY APPLICANT			First Named Inventor	B. Pepinsky	
				Art Unit	1647	
i	(Use as many she ets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	BII-008.02	

	U.S. PATENT DOCUMENTS								
E	examiner Cite	0.3-	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where			
			Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear			
7F	·H/	AA*	US-4,002,531	01-11-1977	Royer				
	1	AB*	US-5,476,653	12-19-1995	Pitt et al.				
		AC*	US-5,747,639	05-05-1998	Seely				
		AD*	US-5,856,451	01-05-1999	Olsen et al.				
		AE*	US-6,048,529	04-11-2000	Atassi et al.				
		AF*	US-6,638,500	10-28-2003	El-Tayar et al.				
	1	AG*	US-20040102381-A1	05-27-2004	Ekwuribe et al.				
	7	AH*	US-20040043002-A1	03-04-2004	El-Tayar et al.				

				FOREIG	GN PATENT D	OCUMENTS		
Exar Initia			Cite No.	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁸ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
7	-H	B.	Α	WO-97/04796	02-13-1997			
	ī	В	В	WO-00/09073	02-24-2000			
	Т	В	C	WO-01/15736	03-08-2001			
	17	В	D	EP-1264837	12-11-2002			
	A	В	E	EP-1564219	08-17-2005			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw tine through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. 'Applicant's unique citation designation number (optional). ³ See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issue the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS	
Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	172
		include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature	/Fozia Hamud/	Date Considered	05/02/2007
Signature		Considered	

^{&#}x27;Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached.

PATENT & TRACE	25205 (5)	k Redu	ction Act of 1995, no persons.	U.S. Patent and Trad	PTO/SB/08a (proved for use through 07/31/2006. OMB 065 emark Office; U.S. DEPARTMENT OF COMM of information unless it contains a valid OMB control o	1-003°
	for form 1449A/PTO)			Complete if Known	
		•		Application Number	10/802,540	
INFO	RMATION	DIS	CLOSURE	Filing Date	March 16, 2004	
STAT	TEMENT B'	Y A	PPLICANT	First Named Inventor	Pepinsky et al.	
				Art Unit	1646	
	(Use as many she	ets as	necessary)	Examiner Name	Not yet known	
Sheet	1	of	2	Attorney Docket Number	BII-008.02	

		U.S. PATENT	DOCUMENTS	
Cite No.1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevan Passages or Relevant Figures Appear
AY	US- 4,414,147	11/08/83	Klibanov et al.	*****
AZ	US- 4,766,106	08/23/88	Katre et at.	-
A1	US- 5,545,723	08/13/96	Goelz et al.	
A2	US- 5,643,575	07/01/97	Martinez et al.	
A3	US- 5,672,662	09/30/97	Harris et al.	
1				
1				
1		-		***************************************
		-		
-				
1				
 			1	
			1	
1	 		 	
 				
+				
 				
	AY AZ A1 A2	Cite No.¹ Number - Kind Code² (if known) AY US- 4,414,147 AZ US- 4,766,106 A1 US- 5,545,723 A2 US- 5,643,575	Cite No.¹ Document Number Publication Date MM-DD-YYYY AY US- 4,414,147 11/08/83 AZ US- 4,766,106 08/23/88 A1 US- 5,545,723 08/13/96 A2 US- 5,643,575 07/01/97	Number - Kind Code ² (if known) Publication Date MM-DD-YYYY

Examiner Initials*	Cite No.1	Foreign Patent Document	S. Milantia	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T°
		Country Code ³ - Number ⁴ - Kind Code ⁶ (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document		
7FH/	во	EP 0 098 110	10/18/89	Europe		
1	BP	EP 0 401 384	03/13/96	Europe		
	BQ	EP 0 822 199	02/04/98	Europe		
	BR	WO 94/05332	03/17/94	PCT		
	BS	WO 95/21629	08/17/95	PCT		
V	BT	WO 98/32466	07/30/98	PCT		
	BU	WO 99/03887	01/28/99	PCT		

A STATE OF THE PARTY OF THE PAR	Name and Address of the Owner, where the Owner, which is the Owne		
Examiner Signature	/Fozia Hamud/	Date Considered	05/02/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional), ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04, ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid CMB control number

Substitute for form 1449B/PTO Complete if Known Application Number 10/802,540 INFORMATION DISCLOSURE Filing Date March 16, 2004 STATEMENT BY APPLICANT First Named Inventor Pepinsky et al. Art Unit 1646 (Use as many sheets as necessary) Examiner Name Not yet known BII-008.02 Sheet Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
/FH/	C1	• Delgado et al., "The Uses and Properties of PEG-Linked Proteins," Critical Reviews in Therapeutic Drug Carrier Systems, 9(3,4):249-304 (1992)			
/FH/	C2	Goodson et al., "Site-Directed Pegylation of Recombinant Interleukin-2 at its Glycosylation Site," Biotechnology, 8:343-346 (1990)			
/FH/	СЗ	Harris et al., "New Polyethylene Glycols for Biomedical Applications," American Chemical Society, Ch. 27, pp. 418-429 (1991)			
/FH/	C4	Morpurgo et al., "Preparation and Characterization of Poly(ethylene glycol) Vinyl Sulfone," Bioconjugate Chem., 7:363-368 (1996)			
/FH/	C5	Zalipsky et al., "Use of Funtionalized Poly(Ethylene Glycol)s for Modification of Polypeptides," Poly(Ethylene Glycol) Chemistry: Biotechnical and Biomedical Applications, Ch. 21:347-367 (1992)			

Examiner	/Fozia Hamud/	Date	05/02/2007
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

m PTO-1449 INFORMA	TION D	DISCLOSURE OTA	TION Dock	et Number (Optional) 08.02 icant		plication Number 802,540	Sheet Page 1 of	
IN AN APPLICATION (Use several sheets if necessary) JIL 2 2 2			Pepir	Pepinsky et al. Elling Date Garch 16, 2004		Group Art Unit 647		
		E		S. PATENT DOCUMENTS				
EXAMINER INITIAL	DOC	CUMENT NUMBERAL	EMBATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
/FH/	АА	5,965,119	10/12/99	Greenwald, et al.			12/30/97	
	АВ	5,874,075	02/23/99	Collins, et al.			03/31/95	
	AC	5,792,834	08/11/98	Hakimi, et al.			06/01/95	
	AD	5,738,846	11/21/95	Greenwald, et al.			04/14/98	
	AE	5,711,944	01/27/98	Gilbert et al.			11/10/94	
	AF	5,702,717	10/25/95	Cha, et al.			12/30/97	
	AG	5,681,811	10/28/97	Martinez, et al.			10/27/93	
	АН	5,529,915	012/12/95	Phillips, et al.			06/25/96	
	Ai	5,382,657	08/26/92	Karasiewicz, et al.			01/17/95	
	AJ	5,359,030	05/10/93	Ekwuribe			10/25/94	
	AK	5,286,637	0-2/15/94	Veronese et al.			01/07/93	
	AL	5,281,698	07/23/91	Nitecki			01/25/94	
	АМ	5,109,120	04/28/92	Ueno, et al.			. 06/09/89	
	AN	4,917,888	04/17/90	Katre, et al.			12/11/87	
	AO	4,894,226	01/16/90	Aldwin, et al.			01/14/86	
	АР	4,751,077	06/14/88	Bell, et al.			11/30/84	
	AQ	4,179,337	12/18/79	Davis, et al.			07/28/77	
	AR	5,252,714	10/12/93	Harris, et al.			11/28/90	
	AS	5,824,784	10/20/98	Kinstler, et al.			10/12/94	
	АТ	5,985,265	11/16/99	Kinstler, et al.			06/20/97	
	AU	5,990,237	11/23/99	Bentley, et al.			05/20/98	
	AV	6,180,095	01/30/01	Greenwald, et al.		·	10/30/98	
1	AW	2001/0011115	06/02/01	Harris, et al.			03/11/99	

EXAMINER

AX

/Fozia Hamud/

05/26/92

5,116,964

DATE CONSIDERED

05/02/2007

11/22/89

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Capon, et al.

Docket Number (Optional) B11-008.02 Application Number 10/802,540 ORMATION DISCLOSURE CITATION Applicant AN APPLICATION Pepinsky et al. Ise everal sheets if necessary) Group Art Unit Filing Date March 16, 2004 FOREIGN PATENT DOCUMENTS Translation THADE **SUBCLASS** DOCUMENT NUMBER DATE COUNTRY **CLASS** YES NO /FH/ BA WO 99/55377 11/04/99 **PCT** ВВ 04/25/96 **PCT** WO 96/11953 BC WO 87/00056 01/15/87 **PCT** Euro. Pat. Off. BD EP 0 229 108 12/27/90 BE EP 0 154 316 09/13/89 Euro. Pat. Off. PCT BF WO 97/18832 11/21/95 ВG WO 98/48840 11/05/98 **PCT PCT** 12/19/97 вн WO 99/32134 Bi WO 99/32139 07/01/99 **PCT** WO 99/32140 07/01/99 **PCT** BJ BK WO 01/46291 06/28/01 **PCT PCT** BL WO 87/00056 01/15/87 вм WO 95/13090 05/18/95 **PCT** WO 99/55377 11/04/99 **PCT** BN **OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages Etc.) GenBank Accession Number: E00029 (September 29, 1997) /FH/ /FH/ Karpusas et al. (1997). Proc Natl. Acad. Sci. USA 94: 11813-11818 /FH/ Runkel et al. (1998). Pharm. Res. 15: 641-649 /FH/ International Search Report for PCT/US99/24201 mailed July 7, 2000 DATE CONSIDERED EXAMINER 05/02/2007 /Fozia Hamud/

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in

conformance and not considered. Include copy of this form with next communication to the applicant.

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERERCE